K031903

MAR - 3 2004

1. 510(K) SUMMARY

Submitter's Name:	Guidant Corporation CRM Division
Submitter's Address:	4100 Hamline Avenue Mail Stop F330 St. Paul, Minnesota 55112
Telephone: **Fax:**	(651) 582-4927 (651) 582-5134
Contact Person:	Stephanie Isgrigg Robinson
Date Prepared:	February 20, 2004
Device Trade Name:	RAPIDO™ Cut-Away™ Bleedback Control Valve
Device Common Name:	Bleedback Control Valve
Device Classification Name:	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass, Hemostasis Valve
Device Classification:	Class II

Summary of Substantial Equivalence:
The design, materials, method of delivery and intended use features of the modified RAPIDO™ Cut-Away™ Bleedback Control Valve is substantially equivalent with regard to these features in their predicate device, COPILOT™ Bleedback Control Valve (K991102/06-09-99)

Device Description:
The RAPIDO™ Cut-Away Bleedback Control Valve is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices such as balloon catheters, wires, and pacemaker and defibrillation leads. The RAPIDO™ Cut-Away Bleedback Control Valve has a single adjustable seal that provides control over fluid loss.

The Bleedback Control (BBC) seal is a diaphragm seal with a thin membrane across the inside diameter that forms around diagnostic/ interventional devices as they move into and out of the vasculature. This seal provides minimal fluid loss while not restricting device movement. The BBC seal is open when the cap is depressed, and closed with the cap is released. An open BBC seal allows air and fluid to be purged and allows the advancement/withdrawal of diagnostic/ interventional devices. The seal can be locked open by rotating the cap an eighth clockwise turn when the cap is depressed. To release the lock the cap is rotated clockwise an eighth of a turn.

Intended Use:
The Guidant Bleedback Control Valve is intended for maintaining a seal around diagnostic/interventional devices with an outside diameter of less than 0.185" in the venous anatomy only, during interventional procedures.

Technological Characteristics:
Comparisons of the proposed and predicate device show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate device.

Performance Data:
The results of the verification testing demonstrate that the modified Bleedback Control Valve meets the established acceptance criteria and perform in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

Conclusions:
The modified Bleedback Control Valve has the same intended use, technological characteristics, and performance properties as the Guidant approved COPILOT Bleedback Control Valve. Therefore, there are no new safety or effectiveness issues. The modified Bleedback Control Valve is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

Guidant Corporation
c/o Ms. Stephanie Isgrigg Robinson
Regulatory Affairs Associate
4100 Hamline Avenue North
St. Paul, MN 55112-57908

Re: K031903
RAPIDO™ Cut-Away™ Bleedback Control Valve – Model 7568
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adapter, Stopcock, Manifold or Fitting
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: February 24, 2004
Received: February 25, 2004

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031903

Device Name: RAPIDO™ Cut-Away™ Bleedback Control Valve

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Car

510(k) Num K031903